US007373939B1

(12) **United States Patent**
DuBois et al.

(10) **Patent No.: US 7,373,939 B1**
(45) **Date of Patent: May 20, 2008**

(54) **TRACHEOTOMY PROCEDURE WITH INTEGRATED TOOL**

(75) Inventors: **Brian R. DuBois**, Redwood City, CA (US); **Luke W. Clauson**, Redwood Shores, CA (US); **Douglas T. Ellison**, Plano, TX (US); **Scott O. Chamness**, Menlo Park, CA (US); **Theodore M. Bender**, Oakland, CA (US)

(73) Assignee: **Cardica, Inc.**, Redwood City, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 180 days.

(21) Appl. No.: **11/367,904**

(22) Filed: **Mar. 3, 2006**

(51) **Int. Cl.**
A61M 11/00 (2006.01)

(52) **U.S. Cl.** **128/207.29**; 128/200.26; 128/305.3

(58) **Field of Classification Search** 128/207.29, 128/200.26, 305.3; 606/153, 151; 623/1.13
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,643,649	A	2/1972	Amato	
3,991,765	A	11/1976	Cohen	
4,182,337	A	1/1980	Nickson	
4,291,690	A	9/1981	Jessen	
4,331,138	A	5/1982	Jessen	
4,556,059	A	12/1985	Adamson, Jr.	
5,048,518	A	9/1991	Eliachar et al.	
5,681,323	A	10/1997	Arick	
6,419,681	B1	7/2002	Vargas et al.	
6,428,550	B1	8/2002	Vargas et al.	
6,673,088	B1	1/2004	Vargas et al.	
2006/0135984	A1*	6/2006	Kramer et al.	606/192

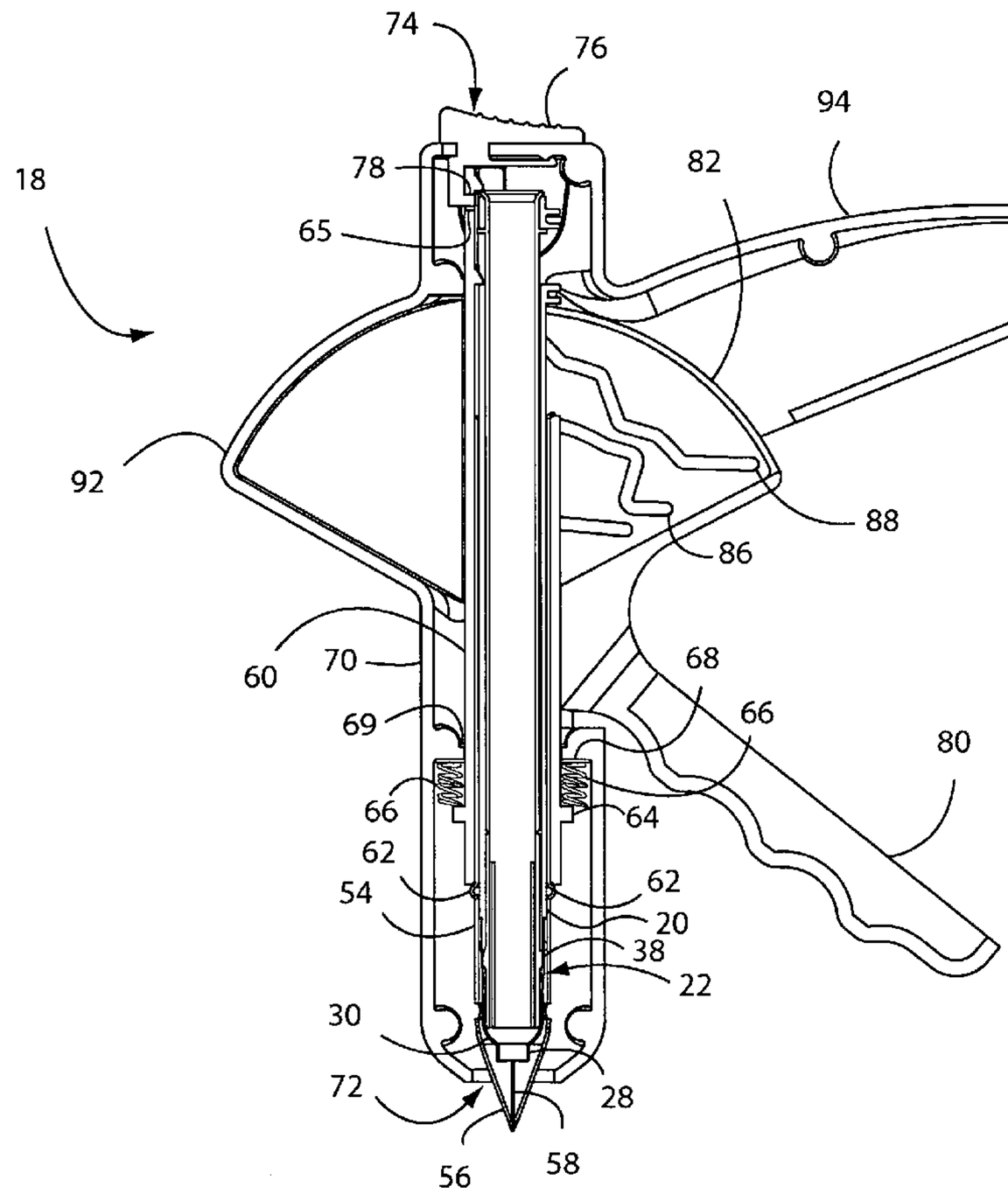
* cited by examiner

Primary Examiner—Steven O. Douglas
(74) *Attorney, Agent, or Firm*—Brian A. Schar

(57) **ABSTRACT**

An integrated tool may be used to perform a tracheotomy. The integrated tool may include a trocar and a delivery mechanism, where the delivery mechanism may deploy a stoma stent. The trocar may be actuated impulsively.

17 Claims, 7 Drawing Sheets



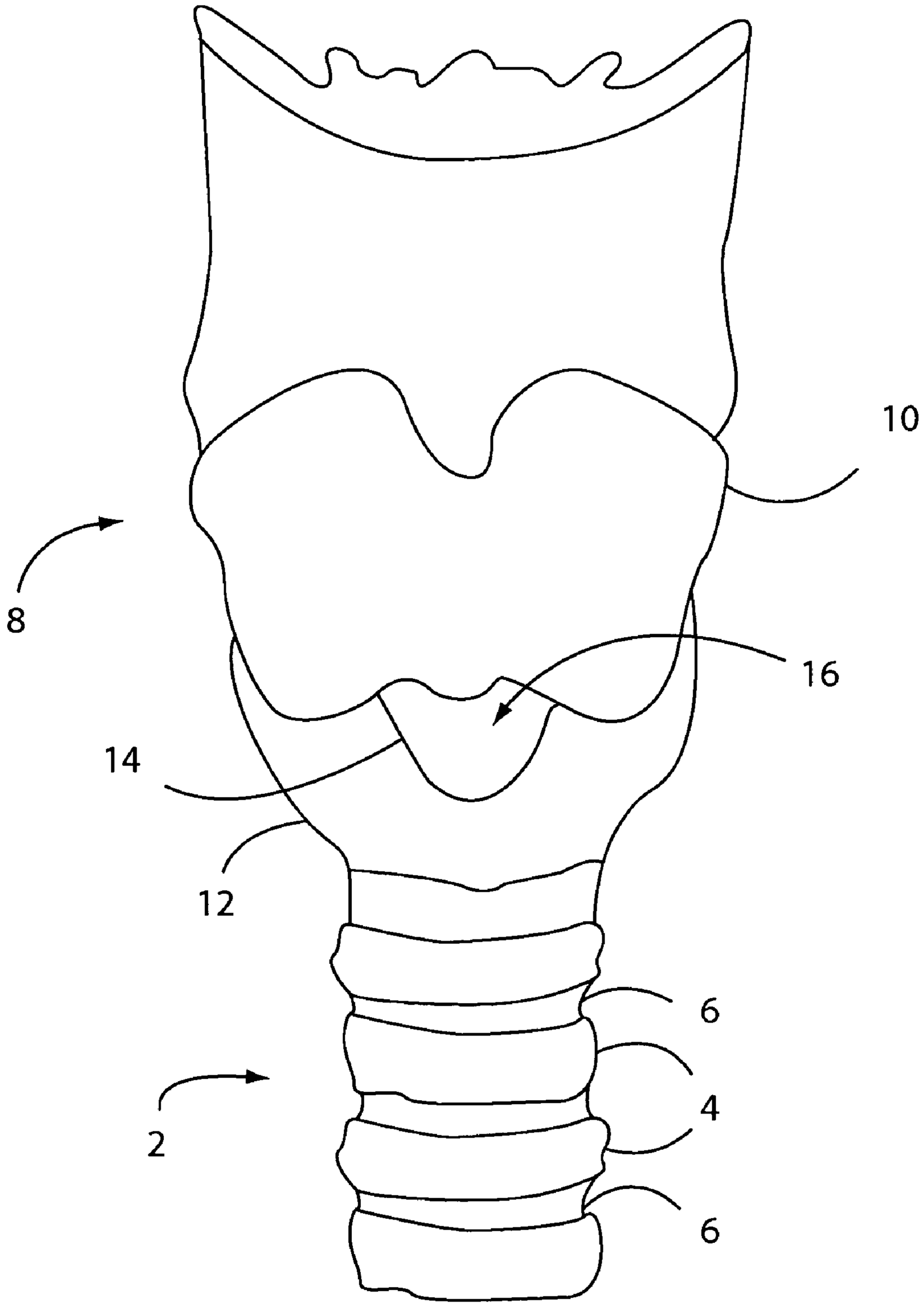


FIG. 1

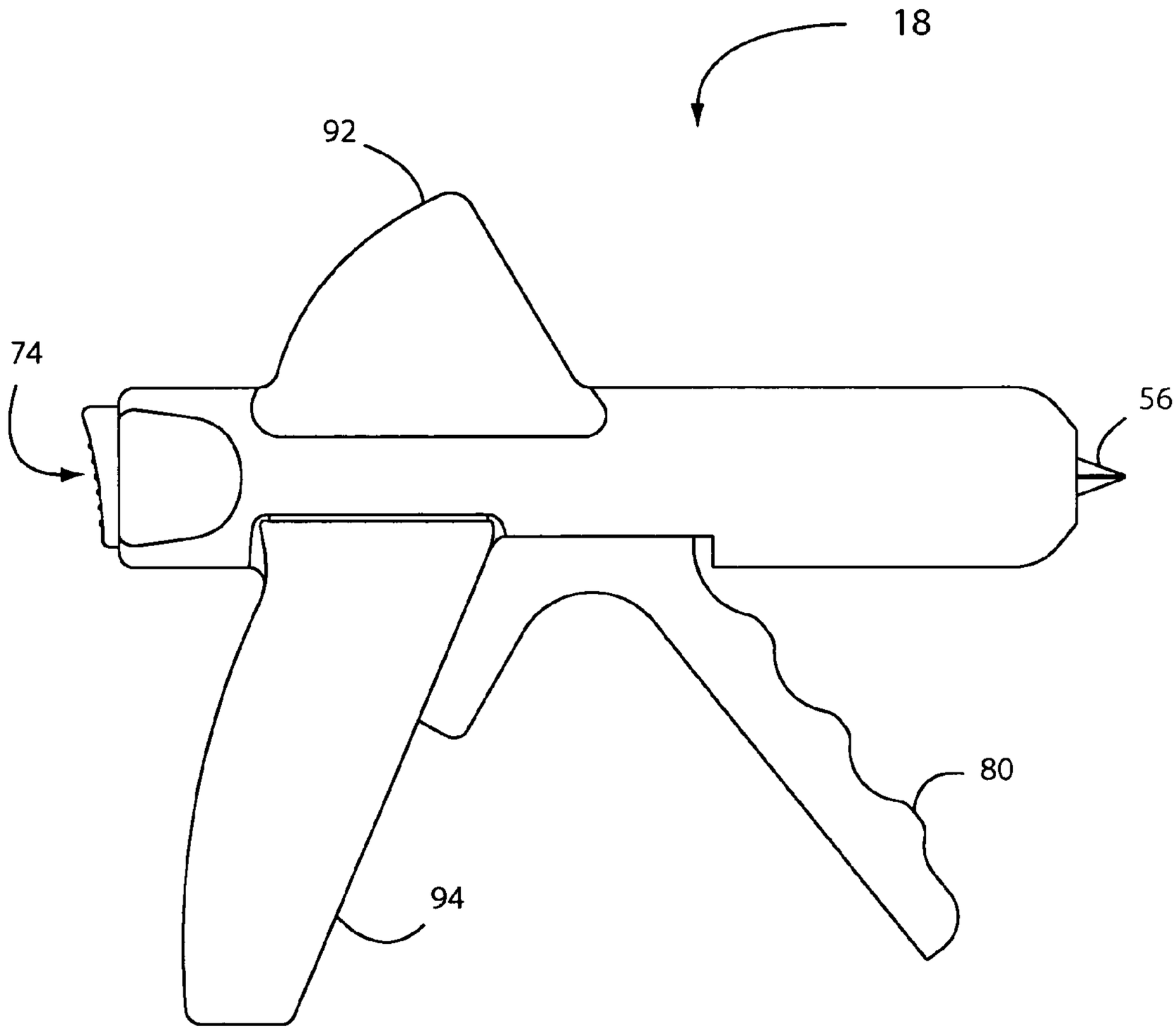


FIG. 2

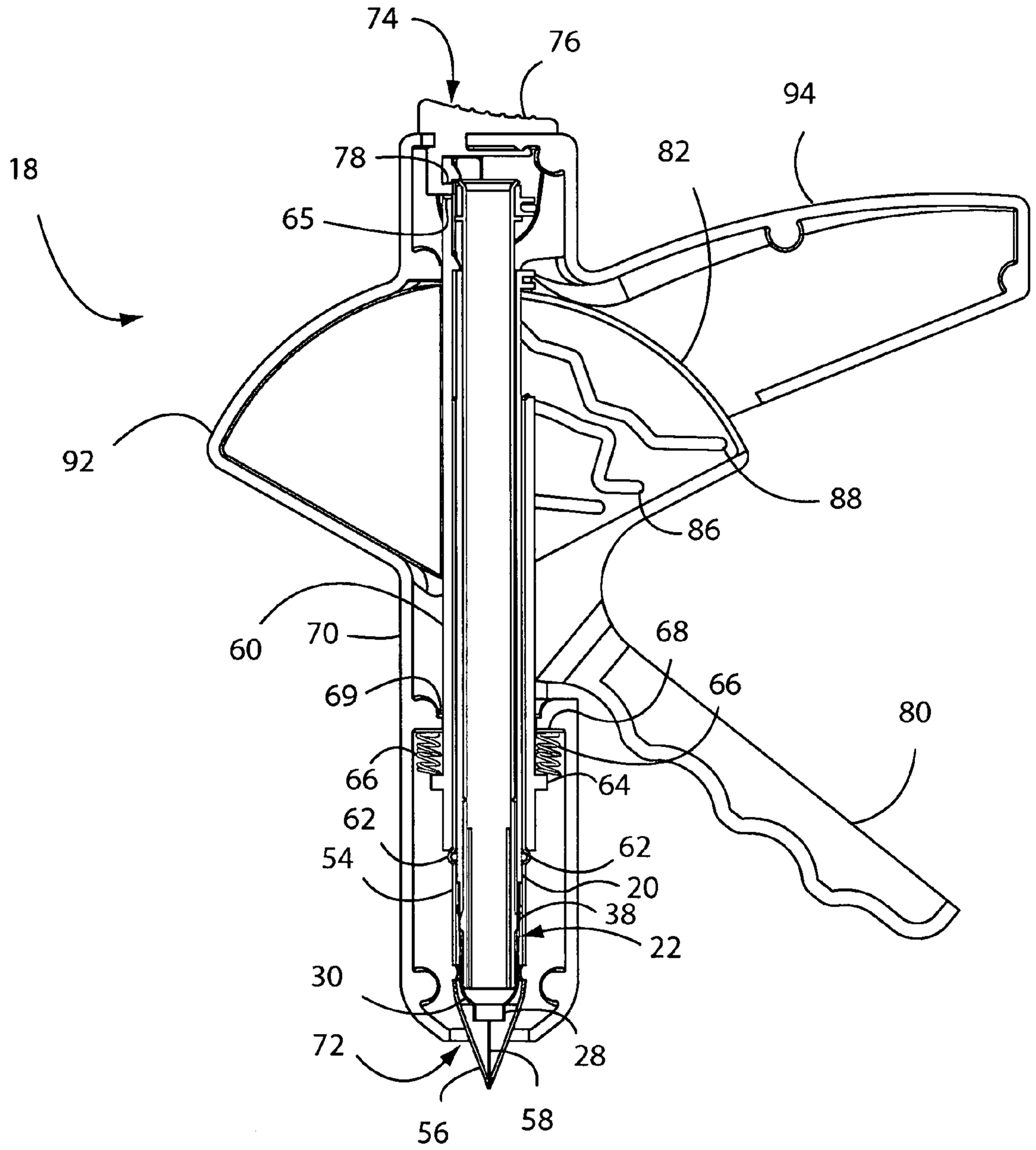

74
76
94
78
82
18
65
92
88
86
60
70
68
69
66
66
80
64
62
62
54
20
38
22
30
72
28
56
58

FIG. 3

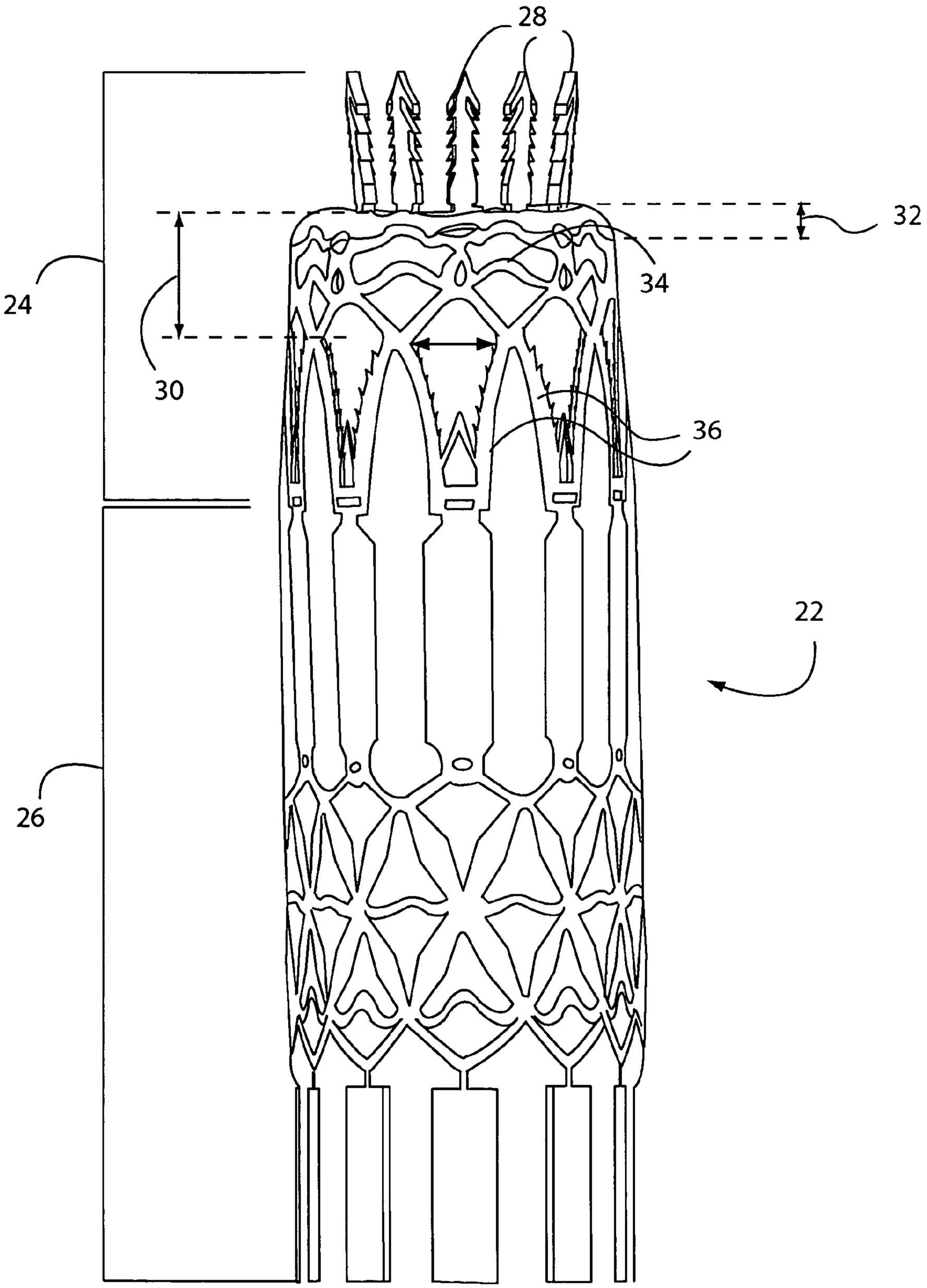


FIG. 4

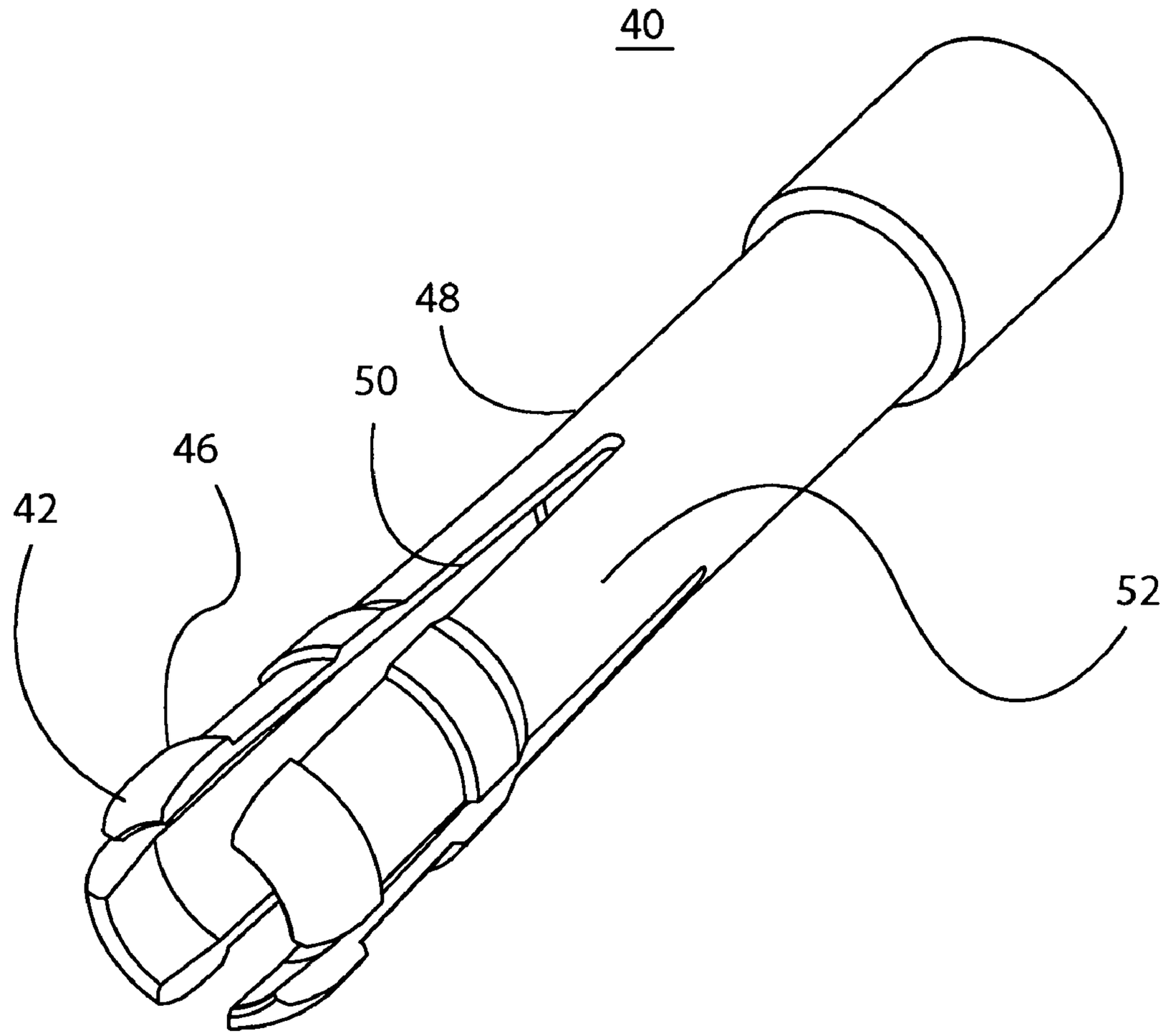


FIG. 5

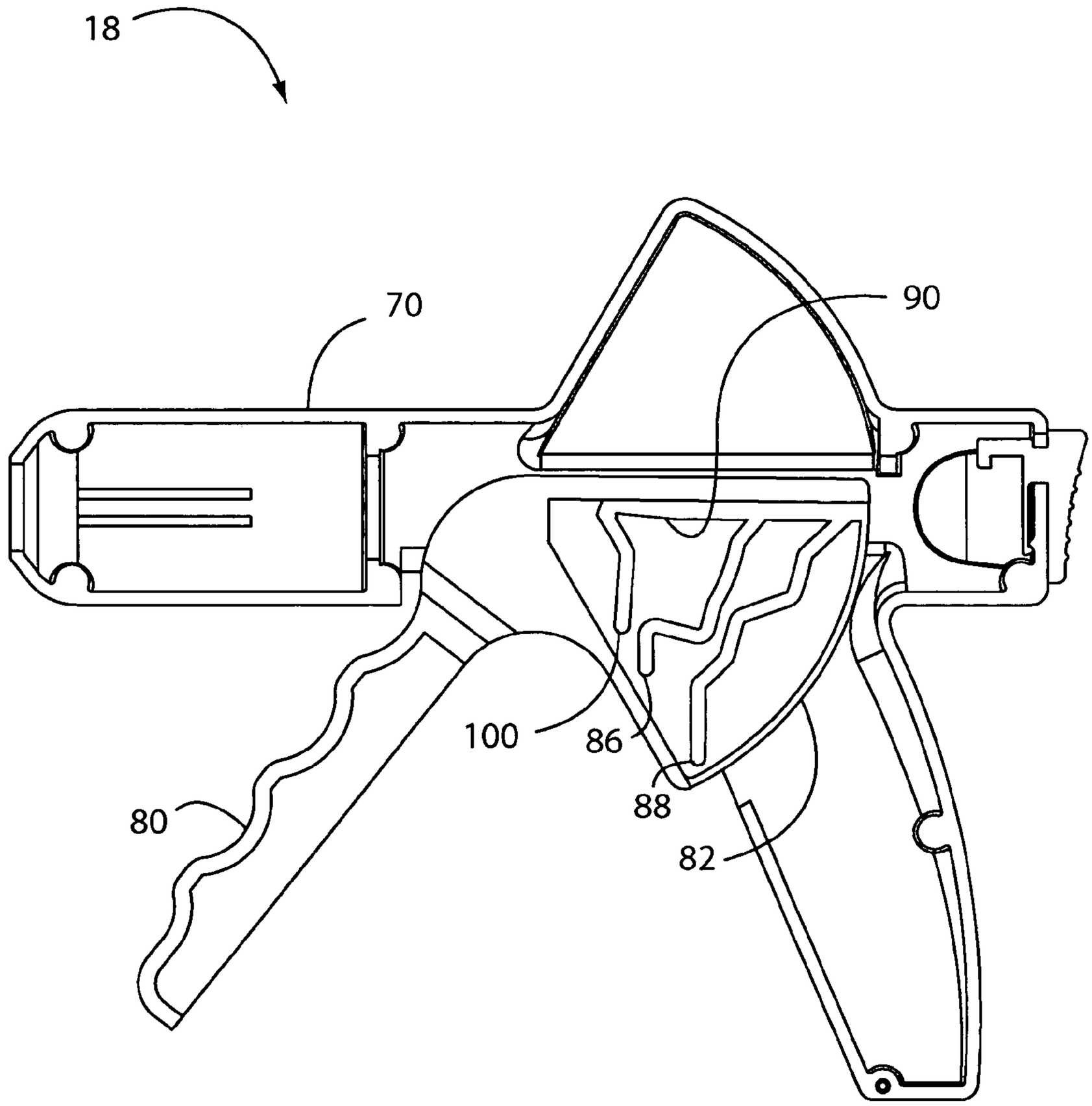


FIG. 6

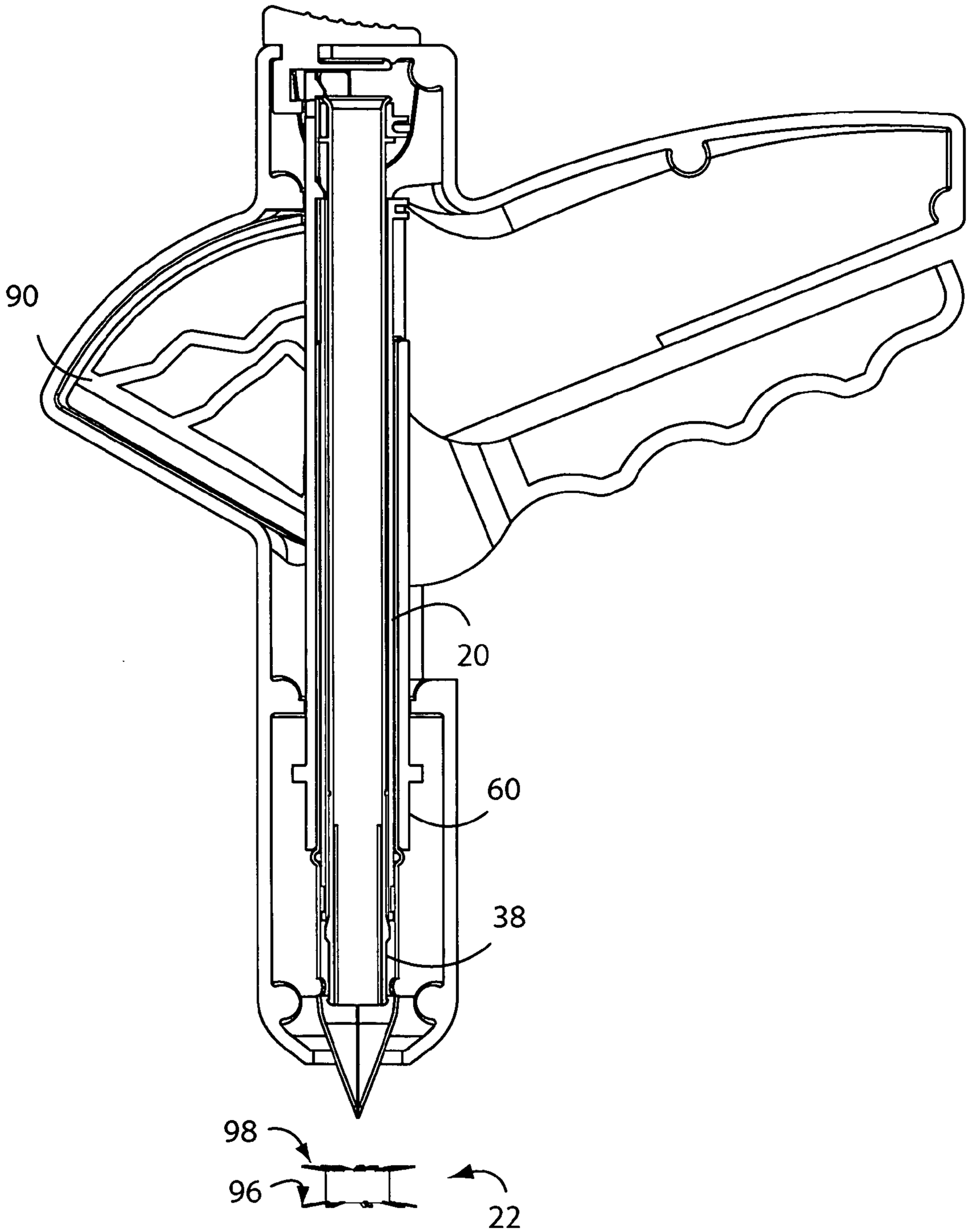


FIG. 7

TRACHEOTOMY PROCEDURE WITH INTEGRATED TOOL

FIELD OF THE INVENTION

The present invention relates generally to surgical procedures, and more particularly to tracheotomy procedures utilizing an integrated tool.

BACKGROUND

A tracheotomy is a surgical procedure in which a cut or opening is made in the trachea. The term tracheostomy is sometimes used interchangeably with tracheotomy, although the word "tracheostomy" generally refers to the opening itself while the word "tracheotomy" generally refers to the actual operation. A tube, cannula, stoma stent or other device may be inserted into the tracheostomy to hold it open, bypass an obstruction and/or allow air to get to the lungs.

Typically, an emergency tracheotomy is performed only as a last-resort procedure, when the patient's trachea is obstructed and the situation is life-threatening. Such an emergency situation may occur, for example, where the trachea is blocked by swelling that results from anaphylactic shock, or from a severe trauma to the neck, nose or mouth, or where the trachea is blocked by the presence of a foreign object in the larynx. A cut is made with a scalpel or any available tool in a thin part of the larynx called the cricothyroid membrane. An endotracheal tube is then inserted through the cut in the cricothyroid membrane, through which the patient can breathe. As popularized on television and in the movies, in dire situations where no other tools are available, a ballpoint pen casing with the ink cartridge removed may be used to penetrate the cricothyroid membrane or other portion of the trachea, and is then left in place to allow the patient to breathe through it. An emergency tracheotomy also is called a cricothyroidotomy. In this document, the terms "tracheotomy" and "cricothyroidotomy" are used synonymously and interchangeably.

Emergency tracheotomies or cricothyroidotomies are generally disfavored, in part due to the potential for error. The person performing the procedure may have minimal or no medical training, and as a result may cause more injury attempting the procedure than would have resulted without it. One potential for error lies in the proper placement of the endotracheal tube, which should be at the cricothyroid membrane and not through the cartilage of the trachea. Another potential for error lies in the inadvertent puncture of the opposite wall of the trachea during performance of the tracheotomy. In addition, placement of a tube, cannula, stoma stent, or similar device in the resultant tracheostomy to prevent it from closing may be difficult, particularly if the person performing the procedure has minimal or no medical training.

Referring to FIG. **1**, the trachea **2** of a patient includes a number of tracheal cartilage rings **4**. Adjacent tracheal cartilage rings **4** are spaced apart from one another and connected by membranes **6**. The larynx **8** is located at the superior end of the trachea **2**. The thyroid cartilage **10** is positioned adjacent to and anterior to part of the larynx **8**. The thyroid cartilage **10** is usually prominent in males, where a portion of it protrudes as the Adam's apple. The cricoid cartilage **12** is located superior to the uppermost tracheal cartilage ring **4**, spaced apart from that ring **4** and connected to it by a membrane **6**. An indentation **14** is present on the anterior surface of the cricoid cartilage **12**, inferior to the thyroid cartilage **10**. The cricothyroid membrane **16** is positioned in that indentation **14**. Although different patients may exhibit variations, the anatomy shown in FIG. **1** is standard.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a front view of the tracheal anatomy.

FIG. **2** is a side view of an integrated tracheotomy tool in a first position.

FIG. **3** is a side cross-section view of the integrated tracheotomy tool of FIG. **1** in an initial configuration.

FIG. **4** is a side view of a stoma stent used in the integrated tracheotomy tool of FIG. **1**, in an initial configuration.

FIG. **5** is a perspective view of an expander tip used in the integrated tracheotomy tool of FIG. **1**.

FIG. **6** is a side view of a cam plate and trigger of the integrated tracheotomy tool in the initial configuration relative to the housing of the integrated tracheotomy tool.

FIG. **7** is a side cross-section view of the integrated tracheotomy tool of FIG. **1** in a final configuration.

The use of the same reference symbols in different figures indicates similar or identical items.

DETAILED DESCRIPTION

Integrated Tracheotomy Tool

Referring to FIGS. **2-3**, an exemplary integrated tool **18** used to perform a tracheotomy is shown, in an initial configuration. As used in this document, the term "tracheotomy" includes any procedure in which an opening is created in any portion of the trachea, such as tracheotomy, cricoidectomy, cricothyrotomy and cricotracheotomy. The integrated tool **18** may include a crown **20** that holds a stoma stent **22** at or near its distal end. The crown **20** may be a tube. Advantageously, the crown **20** is configured in a manner similar to the crown disclosed in commonly-owned U.S. Pat. No. 6,962,595 to Chamness et. al., which is hereby incorporated by reference in its entirety. Alternately, the crown **20** may be configured in any other suitable manner. The crown **20** includes at least one crown cam follower (not shown) extending therefrom. Each crown cam follower may be a pin, stud or any other suitable structure or mechanism. Each crown cam follower may be positioned at any suitable location along the length of the crown **20**.

Referring also to FIG. **4**, advantageously an exemplary stoma stent **22** is configured in a manner analogous to the configuration of the anastomosis device disclosed in U.S. Pat. No. 6,962,595. Advantageously, the stoma stent **22** may be fabricated to have a larger diameter, width and/or thickness than the anastomosis device disclosed in U.S. Pat. No. 6,962,595. The stoma stent **22** may be connected to the crown **20** in any suitable manner. For example, the stoma stent **22** may include a deployable section **24** and a discard section **26** that are frangibly connected to one another. The discard section **26** may be fixed to the crown **20**, such as by welding, adhesive, mechanical connection, or in any other suitable manner. The deployable section **24** may include a plurality of inner flange tines **28** at its distal end. The inner flange tines **28** may be oriented generally longitudinally before the stoma stent **22** is deployed, or may be oriented in any other suitable direction. The proximal end of each inner flange tine **28** may be connected to a linkage **30** that is configured to form the body of the deployable section **24**. The linkage **30** may curve or otherwise protrude inward at its distal end, and that inward-curving or -protruding section of the linkage **30** may be referred to as the ring **32**. The ring

32 and/or a remainder of the linkage **30** may be configured to expand radially during deployment, as is described in greater detail below. Thus, the linkage **30** may include a number of generally circumferentially-positioned expandable members **34**, such that the linkage **30** is free to expand radially upon the application of an appropriate force. A plurality of outer flange arms **36** may be connected to and extend generally proximally from the linkage **30**. The outer flange arms **36**, like the inner flange tines **28** and the linkage **30**, may be configured in any suitable manner. As one example, at least one outer flange arm **36** may be generally V-shaped, with the open end of the V-shape connected to the linkage **30**. The proximal end of each outer flange arm **36** may be frangibly connected to the distal end of the discard section **26**. Optionally, at least the linkage **30** of the stoma stent **22** may be covered with DACRON® brand polyester fiber, PTFE, or any other suitable biocompatible covering or coating. Further, the stoma stent **22** optionally may be coated at least in part with collagen and/or a different substance or substances to minimize bleeding, promote healing or perform any other suitable therapeutic purpose.

At least part of an expander **38** is positioned within the crown **20**. The expander **38** may be generally tubular, and may be substantially coaxial with the crown **20**. The expander **38** may be slidable relative to the crown **20**. Advantageously, the expander **38** is configured in a manner similar to the expander disclosed in U.S. Pat. No. 6,962,595. The expander **38** includes at least one expander cam follower (not shown) extending therefrom. Each expander cam follower may be a pin, stud, or any other suitable structure or mechanism. Each expander cam follower may be positioned at any suitable location along the length of the expander **38**.

Referring also to FIG. **5**, the distal end of the expander **38** may be referred to as the expander tip **40**. The expander tip **40** may include an expander head **42** at or near its distal end. The expander head **42** may have a diameter larger than the diameter of the portion of the expander tip **40** immediately proximal to the expander head **42** The expander head **42** may extend substantially circumferentially around the expander tip **40**. The expander head **42** may include a shoulder **46** at its proximal end, which forms any suitable angle with the surface of the body **48** of the expander tip **40**. The expander tip **40** may have a lumen therethrough and one or more slots **50** defined therein. The slots **50** may extend substantially longitudinally from the distal end of the expander tip **40** through the expander head **42**. The segments **52** of the expander tip **40** between the slots **50** each may be biased outward relative to the axis of the expander tip **40**. If so, the expander head **42** may have a larger outer diameter than the inner diameter of the ring **32** of the stoma stent **22** when one or more segments **52** are at least partially free to move outward as a result of that outward bias. Alternately, the segments **52** are not biased outward relative to the axis of the expander tip **40**. The slots **50** may be spaced evenly, or unevenly, around the circumference of the expander tip **40**. Any suitable number of slots **50** and segments **52** may be provided. A sleeve (not shown) may be positioned around at least part of the expander tip **40**, such as disclosed in U.S. Pat. No. 6,962,595.

A trocar **54** is positioned outside the crown **20**. At least a portion of the trocar **54** is tubular, and is configured to receive at least a portion of the crown **20** therein. The trocar **54** and the crown **20** may be substantially coaxial. Advantageously, the trocar **54**, expander **38** and crown **20** are substantially coaxial with one another. The trocar **54**, expander **38** and crown **20** are arranged in a manner similar to that disclosed in commonly-owned U.S. Pat. No. 6,428,550, which is hereby incorporated by reference in its entirety. The trocar **54** may have a pointed tip **56**, which may be substantially conical, or may be shaped in any other suitable manner. The tip **56** of the trocar **54** may have a plurality of slots **58** defined therein that extend proximally from the distal end of the tip **56** of the trocar **54**, oriented substantially longitudinally or in any other manner. Consequently, segments of the tip **56** of the trocar **54** may be spread apart from one another as a result of contact with the stoma stent **22**, crown **20** and/or expander **38** during distal motion of the crown **20** and/or expander **38**. Initially, at least part of the tip **56** of the trocar **54** may be positioned outside the housing **70** of the integrated tool **18**, extending through an aperture **72** or other opening in the distal end of the housing **70**. Alternately, the tip **56** of the trocar **54** may be positioned differently when the integrated tool **18** is in the initial position; for example, the tip **56** of the trocar **54** may be located entirely within the housing **70**. The trocar **54** includes at least one trocar cam follower (not shown) extending therefrom. Each trocar cam follower may be a pin, stud or any other suitable structure or mechanism. Each trocar cam follower may be positioned at any suitable location along the length of the trocar **54**.

A trocar driver **60** may be positioned around at least part of the trocar **54**. The trocar driver **60** may be substantially tubular, and may be substantially coaxial with the trocar **54**. The trocar driver **60** may be slidable or otherwise movable relative to the trocar **54**. The distal end of the trocar driver **60** may be configured to engage a ridge **62** on the surface of the trocar **54**. The ridge **62** may extend circumferentially around the trocar **54**. Alternately, the ridge **62** may be one or more bumps or other raised areas on the trocar **54**. The ridge **62** extends outward from the surface of the trocar **54** sufficiently far to prevent the distal end of the trocar driver **60** from moving distal to that ridge **62**. That is, as the trocar driver **60** slides distally, the distal end of the trocar driver **60** engages the ridge **62** rather than passing over it. Alternately, the trocar driver **60** may be fixed to the trocar **54** in any suitable manner. Alternately, the trocar driver **60** may be omitted, and one or more features of the trocar driver **60** may be integrated into the trocar **54** itself.

A flange **64** extends outward from the surface of the trocar driver **60** at a location spaced apart from the distal end of the trocar driver **60**. Alternately, the flange **64** may be positioned substantially at any other location on the trocar driver **60**. The flange **64** may extend circumferentially around the trocar driver **60**. Alternately, the flange **64** may be interrupted by one or more spaces, such that the flange **64** includes multiple segments extending from the trocar driver **60**. The trocar driver **60** may include a slot **65** defined therein to receive a tab of a safety switch, which is described in greater detail below. Alternately, the trocar driver **60** may be omitted, and the flange **64** may extend from the trocar **54** itself.

At least one spring **66** may be located between the flange **64** and an inner wall **68** of the housing **70** of the integrated tool **18**. The flange **64** extends far enough outward from the wall of the trocar driver **60** to engage the spring or springs **66** and substantially prevent the spring or springs **66** from moving distal to the flange **64**. Advantageously, the spring or springs **66** are compression springs. Alternately, at least one spring **66** may be of a different type. Alternately, at least one spring **66** may be an extension spring. The integrated tool **18** includes a housing **70** that is at least partially hollow in order to receive at least part of the crown **20**, expander **38**, trocar **54**, trocar driver **60**, spring or springs **66**, and/or other

components therein. The inner wall **68** of the housing **70** may be oriented substantially perpendicular to the longitudinal axis of the trocar driver **60**, or may be oriented in any other suitable manner. The inner wall **68** includes at least one aperture **69** therethrough to allow one or more components that are present in the housing to extend through the inner wall **68**. The inner wall **68** engages the proximal end, or any other suitable portion, of the spring or springs **66**. Alternately, the proximal end of the spring or springs **66** engages or is connected to a structure or mechanism other than the inner wall **68** of the housing **70**. If so, the inner wall **68** of the housing **70** may be omitted, and one or more stubs, tabs or other structures may be utilized instead. In the initial configuration of the integrated tool **18** shown in FIG. **3**, the spring or springs **66** store energy. For example, where the spring or springs **66** are compression springs, the spring or springs **66** are held in compression between the flange **64** and the inner wall **68** of the housing **70** when the integrated tool **18** is in the initial configuration.

Optionally, the integrated tool **18** may include a safety switch **74**. The safety switch **74** may be positioned at the proximal end of the integrated tool **18**, or at any other suitable location on the integrated tool **18**. The safety switch **74** may include an input feature **76** outside the housing **70** of the integrated tool **18**, placed and configured to be actuated by the user. The safety switch **74** may include a tab **78** or other structure connected to the input feature **76**. The tab **78** is positioned such that it can engage the slot **65** of the trocar driver **60** when the integrated tool **18** is in the initial configuration. When the tab **78** engages the slot **65** of the trocar driver **60**, the tab **78** substantially restrains the trocar **54** against distal motion, thereby preventing inadvertent deployment of the trocar **54**.

The integrated tool **18** may include a control such as a trigger **80**. Referring also to FIG. **6**, the trigger **80** is connected to at least one cam plate **82**. Advantageously, two cam plates **82** are provided, spaced apart from one another laterally. Advantageously, the trigger **80** and cam plate or plates **82** are fabricated as a single piece. The trigger **80** and cam plate or plates **82** may rotate as a unit about a pivot point **84** that may be any structure or mechanism that allows the trigger **80** and cam plate **82** to pivot relative to the housing **70**. For example, the pivot point **84** may be an aperture in the trigger **80** or cam plate or plates **82** configured to receive a post (not shown) in or connected to the housing **70** of the integrated tool **18**. As another example, the pivot point **84** may be a post or rod that is configured to engage one or more apertures or depressions (not shown) in the housing **70** of the integrated tool **18**. Alternately, the trigger **80** and the cam plate **82** may move linearly in addition to, or instead or, moving rotationally.

Each cam plate **82** includes one or more cam paths defined therein. Each cam path is configured in any suitable manner to engage a corresponding cam follower as described above. As one example, a cam path in the cam plate **82** may be a slot through or a trough in that cam plate **82** that engages a corresponding cam follower that is configured as a pin. Any suitable number of cam paths may be provided in a cam plate **82**. As one example, each cam plate **82** may include a crown cam path **86** configured to engage the crown cam follower, an expander cam path **88** configured to engage the expander cam follower, and a trocar cam path **100** configured to engage the trocar cam follower. Each cam plate **82** also may include a first path **90** that intersects an end of each of the other cam paths **86**, **88**, **100**. The first path **90** is configured to be substantially parallel to the longitudinal centerline of the crown **20** when the integrated tool **18** is in its initial configuration. In this way, the cam followers are able to slide distally when the trocar **54** is deployed, as described in greater detail below.

The housing **70** may include a cam plate cover **92** that prevents external interference with the cam plate or plates **82** during their motion. The housing **70** may include a handle **94**, such that the user can place the handle **94** in his or her palm and actuate the trigger **80** with his or her fingers.

Operation

To perform a tracheotomy, the patient is placed on his or her back. Advantageously, an object is placed under the patient's neck, and the patient's head is hyperextended. That is, referring also to FIG. **1**, the patient's chin is rotated away from his or her chest, exposing the neck and causing the trachea **2** to move closer to the skin. Next, the site of the tracheotomy is located. The tracheotomy may be performed at the cricothyroid membrane **16**. If so, the cricothyroid membrane **16** may be found by touch: the person performing the procedure feels the skin of the patient and probes with a finger for the indentation **14** in the cricoid cartilage **12**. The cricothyroid membrane **16** is located in that indentation **14** between the thyroid cartilage **10** and the cricoid cartilage **12**. Particularly in male patients, it may be advantageous to locate the Adam's apple by touch, and move slightly inferior to that in order to find the indentation **14**.

Referring also to FIG. **4**, the tip of the trocar **54** of the exemplary integrated tool **18** initially may extend out of the distal end of the housing **70** of that integrated tool **18**. The configuration of the integrated tool **18** prior to its use, as shown in FIG. **3**, is referred to as the initial configuration. When the tip **56** of the trocar **54** is placed against the tracheotomy site and urged distally, the tip **56** of the trocar **54** penetrates the skin of the patient, and may penetrate at least partially the cricothyroid membrane **16**, a membrane between adjacent tracheal cartilage rings **4**, and/or a tracheal cartilage ring itself, depending on the selected tracheotomy site. The distance to which the tip **56** of the trocar **54** penetrates the skin of the patient is limited by contact between the patient's body and the distal end of the housing **70** of the integrated tool **18**. In this way, the trocar **54** acts as a probe to determine whether the distal end of the integrated tool **18** has been properly positioned at the intended tracheotomy site. For example, where the cricothyroid membrane **16** has been selected as the tracheotomy site, the tip **56** of the trocar **54** should easily pass into the cricothyroid membrane **16**; if the tip **56** of the trocar **54** encounters hard tissue, then the distal end of the integrated tool **18** has been positioned at a location other than the intended tracheotomy site. Thus, the tip **56** of the trocar **54** may be used in probing a potential tracheotomy site. In this way, locating the tracheotomy site thus may be performed simultaneously with placing the integrated tool **18** at the tracheotomy site. Alternately, a separate probe may be used to locate the tracheotomy site. Alternately, the tracheotomy may be performed between adjacent tracheal cartilage rings **4** at a location other than the cricothyroid membrane. If so, the adjacent tracheal cartilage rings **4** are found by touch, and the space between those adjacent tracheal cartilage rings **4** is apparent. Alternately, the tracheotomy may be performed directly through at least part of one or more tracheal cartilage rings **4**, which may be necessary or unavoidable in an emergency situation. Alternately, the tracheotomy may be performed as an over-the-wire technique, where a needle is used to determine the ideal location and is inserted at the tracheotomy site. A wire may be advanced through the

needle, after which the needle is removed. The integrated tool **18** then may be advanced over-the-wire to the tracheotomy site.

Next, the integrated tool **18** is actuated to create an opening at the intended tracheotomy site. For clarity, the intended tracheotomy site will be described here and below as the cricothyroid membrane **16**, although this does not limit the possible tracheotomy sites to the cricothyroid membrane **16**. The safety switch **74**, if utilized in the integrated tool **18**, is actuated to remove the tab **78** of the safety switch **74** from the slot **65** of the trocar driver **60**, or to perform any other action that frees the trocar driver **60** to move distally.

The trocar **54** is then fired through the cricothyroid membrane **16**, creating an opening therein. The trocar **54** may be fired by pulling the trigger **80** toward the handle **94**, such that actuation of the safety switch **74** alone does not cause the trocar **54** to fire. For example, a pin or other lockout (not shown) on at least one cam plate **82** may be positioned to engage and hold the trocar driver **60** until the trigger **80** is pulled a small amount to move that pin or lockout out of engagement with the trocar driver **60** and allow it to move distally. Actuation of the trigger **80** frees the trocar driver **60**, and the energy stored in the spring or springs **66** causes the spring or springs **66** to move longitudinally. The movement of the spring or springs **66** against the flange **64** of the trocar driver **60** causes the freed trocar driver **60** to move distally. The distal end of the trocar driver **60** in turn contacts and pushes against the ridge **62** of the trocar **54**, causing the trocar **54** to move distally. Alternately, if the trocar drive **60** is not utilized, the movement of the spring or springs **66** may move the trocar **54** in the distal direction by direct engagement. The spring or springs **66** release enough energy during their expansion to urge the trocar **54** distally to penetrate the cricothyroid membrane **16** or other anticipated tracheotomy site. Advantageously, the trocar **54** is urged in the distal direction as a result of an impulsive force applied to it by the spring or springs **66** or other energy storage mechanism; an "impulsive force" is a force that acts on a body for a short time but produces a large change in its linear or angular momentum. As the trocar **54** moves distally, each trocar cam follower moves along the first path **90** in the corresponding cam plate **82**. Alternately, the trocar **54** may fire automatically when the safety switch **74** is actuated to free the trocar driver **60**, without the need for an input to the trigger **80**. Alternately, any energy storage device may be used in addition to or in conjunction with the spring or springs **66**. As one example, one or more balloons (not shown) may be utilized instead of or in conjunction with the spring or springs **66**, connected to a cartridge of carbon dioxide or other gas. Upon actuation of the safety switch, or after the trigger is pulled a small amount, that gas may rush into the balloon or balloons to push the flange **64** of the trocar driver **60** and thereby move the trocar **54** distally. As another example, a moveable piston (not shown) within a cylinder (not shown) may be used, where the piston is operatively coupled to the trocar **54**. Upon actuation of the safety switch, or after the trigger is pulled a small amount, that gas may rush into the cylinder to push the piston and thereby move the trocar **54** distally.

The integrated tool **18** is configured to move the trocar **54** distally a fixed amount that is less than the inside diameter of the trachea **2**. In this way, the tip **56** of the trocar **54** does not encounter or penetrate the opposite side of the trachea **2** after piercing the cricothyroid membrane **16**. The distance that the trocar **54** travels distally during firing may be controlled in any suitable manner. As one example, the trocar driver **60** includes a cam follower that engages the trocar cam path **100** defined in at least one cam plate **82**, and the interaction between the cam follower and the trocar cam path **100** restricts the distal motion of the trocar driver **60** and thus the trocar **54** during firing. As another example, the flange **64** of the trocar driver **60** may contact the inner surface of the housing **70** adjacent to the aperture **72** in the distal end of the housing **70**. Such contact stops the distal motion of the trocar driver **60** and thus the trocar **54**. Optionally, the trocar **54** may be a safety trocar. Safety trocars are standard in the art, and as one example may be configured in a manner similar to that disclosed in U.S. Pat. No. 5,690,663, which is hereby incorporated by reference in its entirety. The tip **56** of the trocar **54** may be shielded or otherwise rendered safe after the initial penetration of the trachea **2**. Thus, the trocar **54** can travel along a fixed distance during firing without the tip **56** puncturing the rear wall of the trachea **2** in the event that motion of the trocar **54** along that fixed distance causes the tip **56** to encounter that rear wall. As a result, the integrated tool **18** that includes a safety trocar may be used across a spectrum of patients having different depths of tissue between the surface of the skin and the inner surface of the trachea **2**. Alternately, the distance that the trocar **54** travels distally during firing may be adjusted by the user.

After its firing, the trocar **54** is positioned across the cricothyroid membrane **16**. Also at this time, the crown **20** and the expander **38** have advanced distally with the trocar **54**. Such advancement may be performed in any suitable manner. As one example, the crown **20**, expander **38** and trocar **54** are fit together closely enough that frictional force between the crown **20** and the trocar **54** moves the crown **20** distally as the trocar **54** is urged distally by the spring or springs **66**, and in turn frictional force between the expander **38** and the crown **20** moves the expander **38** distally at the same time. As the crown **20** and the expander **38** move distally, their cam followers move along the first path **90** in each cam plate **82** as described above, which may be aligned substantially parallel to the longitudinal centerline of the trocar **54**. Alternately, the crown **20** and the expander **38** may remain in place as the trocar **54** moves distally. Alternately, at least one of the cam followers moves along a cam path separate from the first path **90**.

The user then pulls, or continues to pull, the trigger **80** toward the handle **94**. At this time, the crown cam follower is located adjacent to one end of the crown cam path **86**, the expander cam follower is located adjacent to one end of the expander cam path **88**, and the trocar cam follower is located adjacent to one end of the trocar cam path **100**. Continued motion of the trigger **80** engages the crown cam path **86** with the crown cam follower, engages the expander cam path **88** with the expander cam follower, and engages the trocar cam path **100** with the trocar cam follower. Alternately, at least one cam follower is already in position within the corresponding cam path **86**, **88**, **100**.

As the user continues to pull the trigger **80** toward the handle **94**, engagement between the crown cam follower and the corresponding crown cam path **86** and between the expander cam follower and the corresponding expander cam path **88** advances the crown **20** and the expander **38** distally along the interior of the trocar **54**. The crown **20** and expander **38** may be referred to collectively as the delivery mechanism. As the crown **20** moves distally, a portion of the crown **20** in proximity to its distal end and/or the stoma stent contacts the inner surface of the tip **56** of the trocar **54**. This contact causes the tip **56** of the trocar **54** to split. That is, segments between the slots **58** of the tip **56** move outward

away from the longitudinal centerline of the trocar **54** as a result of the force exerted on the tip **56** by the crown **20** and/or the stoma stent **22**. As the tip **56** of the trocar **54** splits, it increases in diameter. If the tip **56** is located in the cricothyroid membrane **16**, then the increase in its diameter enlarges the opening in the cricothyroid membrane **16**.

Next, the integrated tool **18** is actuated to deploy the stoma stent **22** in the tracheotomy. Advantageously, a single control such as the trigger **80** is used both to create the tracheotomy and to deploy the stoma stent, such that both actions are accomplished with a single input to the single control. The crown **20** and the expander **38** translate substantially together into the tracheostomy. Alternately, the crown **20** and expander **38** move in a different manner into the tracheostomy. The stoma stent **22** is then deployed. Such deployment may be performed in any suitable manner. Advantageously, deployment is performed in a manner analogous to the anastomosis device deployment set forth in U.S. Pat. No. 6,962,595. The crown **20** is held substantially in place, thereby holding the stoma stent **22** substantially in place, as the expander **38** is translated distally. As the expander **38** moves distally, it engages the ring **32** of the stoma stent **22** and applies a force to it. This force causes the stoma stent **22** to deform, deflecting a plurality of inner flange tines **28** of the stoma stent **22** outward away from the longitudinal centerline of the stoma stent **22** and forming an inner flange **96**. The ring **32** may expand radially as well as a result of lateral force exerted against it as the expander head **42** moves distally into and/or through the ring **32**. The crown **20**, expander **38** and trocar **54** are then moved proximally together until the inner flange **96** seats against the inner surface of the cricothyroid membrane **16**. This proximal motion may be caused and controlled by motion of the cam plate **82**. One or more of the inner flange tines **28** may penetrate the tissue of the cricothyroid membrane **16** to better hold the stoma stent **22** in place. Alternately, the trocar **54** is moved proximally prior to deployment of the inner flange. If so, the inner flange **96** may be deployed directly onto the inner surface of the cricothyroid membrane **16**, such that the crown **20** and expander **38** need not be translated proximally after deployment of the inner flange **96**.

Next, the trocar **54** is moved proximally out of the opening of the cricothyroid membrane **16**, if it has not been moved out of the opening in the cricothyroid membrane **16** during deployment and/or seating of the inner flange **96** of the stoma stent **22**. The expander **38** is then held in place and the crown **20** is advanced. Advancement of the crown **20** pushes the stoma stent **22** against the shoulder **46** of the expander head **42**, thereby applying a compressive force to the undeployed portion of the stoma stent **22**. This compressive force causes a plurality of outer flange arms **36** to deflect outward away from the longitudinal centerline of the stoma stent **22** and form an outer flange **98**. The stoma stent **22** may be configured in any suitable manner to cause such deflection of the outer flange arms **36**. As one example, referring to U.S. Pat. No. 6,962,595, the intersection of each outer flange arm **36** and the discard section **26** may be further from the longitudinal centerline of the stoma stent **22** than both the distal end of each outer flange arm **36** and a portion of the discard section **26** proximal to and spaced apart from the distal end of the discard section **26**. As a result, an outward moment is produced on the stoma stent **22** at the intersection of each outer flange arm **36** and the discard section **26** as a result of the axial compressive stress exerted on the stoma stent **22**. That outward moment deploys the outer flange arms **36**, and also causes buckling at the intersections between the outer flange arms **36** and the discard section **26**, releasing the deployable section **24** from the discard section **26**. Alternately, the outer flange arms **36** are deployed in a different manner. Alternately, the discard section **26** is omitted, and the entire stoma stent **22** is deployed into the patient without separation of any part of the stoma stent **22** from any remaining part of itself. The outer flange **98** is deployed onto the skin of the patient. One or more of the outer flange tines **98** may penetrate the skin to better hold the stoma stent **22** in place. The deployed stoma stent **22** may compress tissue between the inner flange **96** and the outer flange **98**. In this way, the stoma stent **22** may hold itself securely in place in tissue with a thickness throughout a wide range, thereby facilitating its use across a broad spectrum of patients.

The expander **38** is then withdrawn through the center of the stoma stent **22**, and the integrated tool **18** is removed from the patient. The integrated tool **18** is now in the final configuration, as shown in FIG. **7**.

At this point, the stoma stent **22** has been deployed in the tracheostomy. The deployed stoma stent **22** holds the tracheostomy open. The inner flange tines **28** and outer flange arms **36** hold the stoma stent **22** in place relative to the tracheostomy. Further, tissue positioned between the inner flange tines **28** on the one side and the outer flange arms **36** on the other side is compressed, thereby reducing or eliminating any bleeding at the tracheostomy. The stoma stent **22** may simply be left as is in the patient, without any intubation through the stoma stent **22** into the trachea **2**. If desired, an endotracheal tube, cannula or other structure can be inserted through the stoma stent **22** into the trachea **2**. The stoma stent **22** protects the tracheostomy and allows for convenient exchange of tubes, cannulas or other structures therethrough, as deemed necessary by a medical care provider. Alternately, a tube, cannula or other structure is fixed or may be fixed to the stoma stent **22**.

At a later time, the stoma stent **22** may be removed from the patient, if desired. To do so, a forceps or other instrument is used to deflect the outer flange arms **36** back toward their original position. The forceps or other instrument is then used to pull the stoma stent **22** out of the tracheostomy. As the stoma stent **22** is pulled outward, the inner flange tines **28** deflect back toward their original position, allowing the stoma **22** to be removed. The tracheostomy is then patched and/or closed in a standard manner.

While the invention has been described in detail, it will be apparent to one skilled in the art that various changes and modifications can be made and equivalents employed, without departing from the present invention. It is to be understood that the invention is not limited to the details of construction, the arrangements of components and/or the details of operation set forth in the above description or illustrated in the drawings. Headings and subheadings are for the convenience of the reader only. They should not and cannot be construed to have any substantive significance, meaning or interpretation, and should not and cannot be deemed to be limiting in any way, or indicate that all of the information relating to any particular topic is to be found under or limited to any particular heading or subheading. The contents of each section of this document are merely exemplary and do not limit the scope of the invention or the interpretation of the claims. Therefore, the invention is not to be restricted or limited except in accordance with the following claims and their legal equivalents.

What is claimed is:

1. A method for performing a tracheotomy on a trachea of a patient, comprising:

providing an integrated tool including a trocar and a delivery mechanism movable within said trocar;

storing energy within said integrated tool;

releasing at least part of said stored energy, wherein said releasing applies an impulsive force in the distal direction to said trocar such that said trocar creates an opening in the trachea; and

deploying a stoma stent in the opening with said delivery mechanism.

2. The method of claim **1**, wherein said delivery mechanism includes a crown configured to hold said stoma stent and an expander movable relative to said crown.

3. The method of claim **1**, wherein said integrated tool includes a control; further comprising actuating said control, wherein said creating and said deploying are both performed in response to said actuating.

4. The method of claim **3**, wherein said actuating is performed with a single input.

5. The method of claim **1**, wherein said creating includes penetrating tissue with the distal end of said trocar and expanding the distal end of said trocar.

6. The method of claim **1**, wherein said creating is performed through the cricoid membrane.

7. The method of claim **1**, further comprising holding the opening open after said creating and during at least part of said deploying.

8. The method of claim **1**, wherein said deploying includes expanding a diameter of at least part of said stoma stent.

9. The method of claim **1**, wherein said stoma stent includes a deployable section and a discard section connected to and proximal to said deployable section; and wherein said deploying includes separating said deployable section from said discard section.

10. A method for performing a tracheotomy on a trachea of a patient, comprising:

providing an integrated tool;

creating an opening in the trachea with said integrated tool;

placing a stoma stent in the opening with said integrated tool, said stoma stent including a plurality of inner flange tines and a plurality of outer flange tines; and

deploying said stoma stent, wherein said deploying includes deploying said inner flange tines to create an inner flange positioned within the trachea and deploying said outer flange tines to create an outer flange positioned outside the trachea wherein said creating and said deploying are performed in response to a single input.

11. The method of claim **10**, wherein said integrated tool includes an expander, at least part of which is within said stoma stent; and wherein said deploying includes translating said expander relative to said stoma stent.

12. The method of claim **10**, further comprising compressing tissue between said inner flange tines and said outer flange tines.

13. The method of claim **10**, wherein said deploying deploys said inner flange tines before said outer flange tines.

14. The method of claim **10**, further comprising inserting a tube through said stoma stent into the trachea.

15. A method for performing a tracheotomy on a trachea of a patient, comprising:

providing a tool including a safety trocar;

applying an impulsive force to said safety trocar to create an opening in the trachea with said safety trocar; and

deploying a stoma stent in the opening with said tool;

wherein said creating and said deploying are performed in response to a single input.

16. The method of claim **15**, wherein said tool includes a cam plate, and wherein said creating and said deploying are controlled by said cam plate.

17. The method of claim **1**, wherein said integrated tool includes a housing in which at least part of said trocar is received, said housing defining an opening through which said trocar extends distally; and wherein said releasing causes said trocar to move distally through said opening relative to said housing.

* * * * *